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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,216	10/31/2003	Martin T. Gerber	P-11611.00	1508

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,216	GERBER ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/31/03, 6/5/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the reference to Patent "6,190,648" should read - - 6,190,684 - -.

Appropriate correction is required.

Claim Objections

2. **Claims 4-6, 15 and 19** are objected to because of the following informalities:

3. **Claim 4**:

a. The recitation "submucosa and the musculature" in line 3 should read - - submucosa or the musculature - -.

b. The recitation "prosthesis in pocket" in line 4 should read - - prosthesis in the pocket - -.

4. **Claim 5**:

a. The recitation "away from musculature" in line 1 should read - - away from the musculature - -.

5. **Claim 6**:

a. The recitation "a pocket" in line 2 should read - - the pocket - -.

b. The recitation "submucosa and the musculature" in line 1 should read - - submucosa or the musculature - -.

c. The recitation "needle through mucosa" in line 4 should read - - needle through the mucosa - -.

6. **Claim 15**:

a. The recitation "the prosthesis" in line 2 should read - - the bulking prosthesis - -.

7. **Claim 19**:

a. The recitation "tip comprised" in line 1 should read - - tip comprises - -.

b. The recitation "tip and a wedge-shaped tip" in line 2 should read - - tip or a wedge-shaped tip - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 9-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Silverman et al. (Patent 6358197 B1).

10. **Claim 9**: Silverman et al. (Patent 6358197 B1) teaches a system comprising: a needle (96,52) to make a hole through a mucosa (246) proximate to an anal sphincter (as described in lines 42-43 of column 20); a tubular instrument (96, 52) having a distal end and an opening (108) at the distal end (96b); and a pushing agent (180) to push a bulking prosthesis (337) through the tubular instrument (96, 52) and through the hole in

the mucosa (246, 248) (as described in lines 47-53 of column 17) (as seen in Figures 3, 4, 6, 20 and 26).

11. **Claim 10**: Silverman et al. (Patent 6358197 B1) teaches the system of claim 9, as described above, further comprising: a source of vacuum pressure (220) (as described in lines 29-31 of column 13); and a conduit (92, 232) (as described in lines 63-65 of column 4, and lines 3-5 of column 14) to deliver the vacuum pressure from the source (220) to the mucosa (246, 248) (as seen in Figure 6) (as described in lines 18-25 of column 16).

12. **Claim 11**: Silverman et al. (Patent 6358197 B1) teaches the system of claim 10, wherein the conduit (92, 232) comprises a distal end with a cavity (227) at the distal end to receive the mucosa (246, 248) when the cavity (227) is positioned proximate to the mucosa (246, 248) and the vacuum pressure is delivered to the mucosa (246) (as seen in Figure 6) (as described in lines 18-25 of column 16).

13. **Claim 12**: Silverman et al. (Patent 6358197 B1) teaches the system of claim 9, as described above, wherein the tubular (96, 52) instrument comprises the needle (96, 52) (as seen in Figures 3, 4, and 6).

14. **Claims 13-15, 18-19 and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (Patent 5824086).

15. **Claim 13**: Silvestrini teaches a device comprising: a bulking prosthesis in the shape of a partial cylinder having an inner radius (as seen in Figures 8A-8C), wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the

presence of water (as described in lines 26, 33-36, and 43-47 of column 6), and wherein the inner radius of the partial cylinder (as seen in Figures 8A-8C) is sized to conform to close the anus of a patient.

16. **Claim 14**: The device of claim 13, wherein the bulking prosthesis has a substantially half-cylinder shape (as seen in Figures 8A-8C).

17. **Claim 15**: The device of claim 13, wherein the bulking prosthesis assumes one of a miniature state and an enlarged state (as described in lines 43-47 of column 6), and the prosthesis assumes the shape of the partial cylinder in the enlarged state (as seen in Figures 8A-8C).

18. **Claim 18**: Silvestrini teaches a device comprising: a rod-like bulking prosthesis having a sharpened tip (as seen in Figures 4-7 and 9), wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water (as described in lines 26, 33-36, and 43-47 of column 6).

19. **Claim 19**: Silvestrini teaches the device of claim 18, as described above, wherein the sharpened tip comprises a conical tip (as seen in Figures 4-7 and 9).

20. **Claim 21**: Silvestrini teaches the device of claim 18, as described above, wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water (as described in lines 26, 33-36, and 43-47 of column 6), and wherein the rod-like bulking prosthesis has a width of at least 0.005 to 0.250 inches, or 0.127 to 6.35 millimeters, and thus a length of at least four millimeters in the enlarged state (as described in lines 46-52 of column 5).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. **Claims 1-4 and 6-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman (Patent 6251063 B1) in view of Sawhney (PGPUB 2001/0046518 A1).

23. Silverman et al. (Patent 6251063 B1) teaches a method comprising: implanting a bulking prosthesis (337, 371) in tissue proximate to an anal sphincter (356) (as seen in Figure 19, 21 and 22), wherein the tissue comprises at least one of a submucosa and a musculature (202) underlying the submucosa (as seen in Figure 9 of Silverman et al.). Silverman et al. further teaches that implanting the bulking prosthesis (337, 371) comprises: penetrating a mucosa (196) proximate to the tissue with a syringe (366) needle (368) (as seen in Figures 21 and 23 of Silverman et al.) thereby forming a hole in the mucosa (196); drawing a mucosa (196) away from a musculature (201) underlying a submucosa (as seen in Figures 7 and 9); forming a pocket (227) in one of the submucosa and the musculature (201); and implanting the bulking prosthesis (337, 371) in pocket (227) (as seen in Figures 7 and 9) (as described in lines 30-37 and 64-67 of column 15 of Silverman et al.), through the syringe (366) needle (368) (as described in lines 21-26 of column 28 and 13-19 of column 29 of Silverman et al.).

24. However, Silverman et al. does not teach that the bulking prosthesis (337) enlarges after implantation.

25. Sawhney teaches a bulking prosthesis that is in a miniature state at the time of implantation and assumes an enlarged state after implantation (as described in lines 4-6 of paragraph [0026]), wherein the bulking prosthesis comprises a material that absorbs fluid from the tissue to assume the enlarged state (as described in lines 4-6 of paragraph [0026]) which in one embodiment is a hydrogel (as described in lines 1-5 of paragraph [0001]).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a bulking prosthesis similar to that of Sawhney in a method similar to that of Silverman et al. because the bulking prosthesis of Sawhney does not rely on precipitation of the implant from an injected solution. The precipitation of bulking particles within the injection site relies on a chemical reaction within the body (as described in lines 58-60 of column 12 of Silverman et al.). If a mistake is made concerning the composition of the solution, the procedure may require adjustment, repair or replacement of the implant.

27. Furthermore, the bulking prosthesis of Sawhney swells to a size sufficient to lodge it within the tissue and seal against leakage of fluids (as described in lines 11-13 of paragraph [0028] of Sawhney). A precipitation reaction does not guarantee a specific sized implant and if small particles precipitate they may dissipate and migrate away from the site of implantation.

28. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Silverman et al. (Patent 6251063 B1) and Sawhney (PGPUB 2001/0046518 A1) as applied to claims 1 and 4 above, in view of Silverman et al. (Patent 6358197 B1).

29. The combination of Silverman et al. (Patent 6251063 B1) and Sawhney teaches the method of claim 4, as described above, comprising implanting a bulking prosthesis, which enlarges after implantation, in a pocket formed between the mucosa and muscle tissue proximate an anal sphincter. This combination does not teach the use of vacuum pressure.

30. Silverman et al. (Patent 6358197 B1) teaches a method of implanting a bulking prosthesis comprising drawing the mucosa (246, 248) away from musculature (252, 254) underlying the submucosa (256) by applying vacuum pressure (as described in lines 1-3 of the abstract and lines 53-57 of column 14) to an instrument proximate to the mucosa (246,248) (as seen in Figures 6 and 7).

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method as taught by the combination of Silverman et al. (Patent 6251063 B1) and Sawhney using vacuum pressure as taught by Silverman et al. (Patent 6358197 B1) because it allows a physician to shape the target tissue into protrusions and form implants in the protrusions which have a consistent and predetermined size and shape (as described in lines 51-54 of column 20 of Silverman et al. (Patent 6358197 B1)).

32. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (Patent 5824086) in view of Capecchi et al. (Patent 5489300).

33. Silvestrini teaches the device of claim 13, as described above, comprising a bulking prosthesis in the shape of a partial cylinder wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel. However, Silvestrini does not teach Dacron mesh surrounding the hydrophilic polymer.

34. Capecchi et al. teaches the use of Dacron mesh to surround an implant (as described in lines 37-38 of column 1).

35. It would have been obvious to one of ordinary skill in the art at the time of the invention to surround the hydrophilic polymer of Silvestrini with Dacron mesh as taught by Capecchi et al. because it promotes tissue ingrowth which will secure the bulking prosthesis (as described in lines 34-36 of column 1 of Capecchi et al.).

36. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (Patent 5824086) in view of Van Bladel et al. (Patent 7049346 B1).

37. Silvestrini teaches the device of claim 13 as described above, comprising a bulking prosthesis in the shape of a partial cylinder wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel. However, Silvestrini does not teach that the bulking prosthesis includes a radiopaque material.

38. Van Bladel et al. teaches a bulking prosthesis that comprises a hydrophilic polymer that forms a hydrogel further comprising a radiopaque material (as described in lines 18-23 of column 6).

39. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the bulking prosthesis of Silvestrini with a radiopaque material as taught by Van Bladel et al. because the radiopaque materials allow for monitoring of the treatment site by imaging means including x-ray imaging (as described in lines 25-30 of column 6 of Van Bladel et al.).

40. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (Patent 5824086) in view of Tu et al. (PGPUB 2002/0188308 A1).

41. Silvestrini teaches the device of claim 18 as described above, comprising a rod-like bulking prosthesis having a sharpened tip, which comprises a hydrophilic polymer that forms a hydrogel. However, Silvestrini does not teach that the bulking prosthesis has a helical thread.

42. Tu et al. teaches a bulking prosthesis comprising a helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34).

43. It would have been obvious to one of ordinary skill in the art to make the bulking prosthesis of Silvestrini with helical threads as taught by Tu et al., and which are commonly used in the art, because the threads help to anchor the device within the tissue after implantation (as described in lines 3-5 of paragraph [0162] of Tu et al.).

44. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (Patent 6098629) in view of Hague et al. (PGPUB 2002/0072720 A1).

45. Johnson et al. teaches a method for manufacturing a bulking prosthesis comprising: providing a rod-like bulking prosthesis (as seen in Figures 3-6) that comprises a hydrophilic polymer that forms a hydrogel in the presence of water (as described in claim 14). However, Johnson et al. does not teach the formation of a sharpened tip on an end of the bulking prosthesis.

46. Hague et al. teaches the formation (as described in lines 28-37 of paragraph [0037]) of a sharpened tip (26) on an end of a device to be inserted into the tissues of a patient (as described in lines 10-13 of paragraph [0036]).

47. It would have been obvious to one of ordinary skill in the art at the time of the invention to manufacture the bulking prosthesis of Johnson et al. with the sharpened tip of Hague et al. because it separates the tissue at the implant site, reduces the pressure required for penetration of the skin and may be made of dissolvable material so that it does not cause irritation after the prosthesis has been implanted (as described in lines 13-15 of paragraph [0036] and lines 37-39 of paragraph [0037]).

48. **Claims 23 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Johnson et al. (Patent 6098629) and Hague et al. (PGPUB 2002/0072720 A1) as applied to claim 22 above, and further in view of Boyd et al. (PGPUB 2001/0010021 A1).

49. The combination of Johnson et al. and Hague et al. teaches the method of claim 22, as described above, comprising the formation of a sharpened tip on a bulking prosthesis. This combination also teaches the formation of surface textures, coatings or

structures to resist migration of the bulking prosthesis (as described in lines 1-6 and 10-16 of column 8 of Johnson et al.), but it does not specifically teach the formation of a slot. Additionally this combination teaches the use of various retention structures around the bulking prosthesis (as described in lines 1-6 and 10-16 of column 8 of Johnson et al.), it does not specifically teach the machining of a helical thread.

50. Boyd et al. teaches a method for manufacturing a bulking prosthesis comprising forming a slot (62, 52) in the bulking prosthesis (50) (as seen in Figures 5 and 6), and machining a helical thread around the bulking prosthesis in an alternative embodiment (as described in lines 3-7 of paragraph [0031] and 3-6 of paragraph [0039]).

51. It would have been obvious to one of ordinary skill in the art at the time of the invention to manufacture a bulking prosthesis similar to that of the combination of Johnson et al. and Hague et al. with a slot and/or the helical threading similar to those taught by Boyd et al. because a slot and/or helical threading will facilitate tissue ingrowth around the prosthesis, which secures the prosthesis within the implantation site and promotes healing of the surrounding tissue (as described in lines 14-18 of paragraph [0009] of Boyd et al.

52. **Claims 25-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (PBPUB 2002/0091295 A1).

53. Wilk teaches a method for implanting a bulking prosthesis comprising: implanting a rod-like bulking prosthesis (24, 52) having a sharpened tip (as seen in Figure 5), the bulking prosthesis (24, 52) engaged with an application device (14), rotating the bulking

prosthesis with the application device to ensure proper positioning (as described in lines 12-15 of paragraph [0056], as seen in Figures 1A-1C); and withdrawing the application device (14) (as seen in Figures 1A-1C) comprising disengaging the bulking prosthesis from application device, as the bulking prosthesis is left in the tissue after the application device is removed (as seen in Figures 1A-1C).

54. While a particular tissues of the body are not specified, it was disclosed and would have been obvious to one of ordinary skill in the art at the time of the invention that this method can be used in any tissue of the body, including tissue proximate to an anal sphincter (BW) as described in one embodiment (as described in lines 9-12 of paragraph [0057]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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